7/16/04

162 Date

1617

CASE 4-118-8353B

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV540541345 July 15, 2004

Express Mail Label Number Date of Deposit

#20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

NEUER ET AL.

APPLICATION NO: 09/738,212

FILED: DECEMBER 15, 2000

FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID

Art Unit: 1617

Examiner: L. Wells

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 CFR 1.181 TO WITHDRAW HOLDING OF ABANDONMENT OF APPLICATION

Sir:

A Notice of Abandonment was mailed on March 15, 2004 for the above-identified application. A copy of the Notice is enclosed herewith.

Box 6 of the Notice was checked. The reason given in Box 6 for the holding of abandonment was:

"The decision by the Board of Patent Appeals and Interference (BPAI) rendered on November 10, 2003 and because the period for seeking court review of the decision has expired and there are no allowed claims."

In response to the Notice of Abandonment, Applicants contacted the Examiner in charge of the above case on April 29, 2004 to discuss the reasons for the Notice of Abandonment. Applicants explained to the Examiner that a reply accompanied by a terminal disclaimer and postcard were timely filed with the U.S. PTO on January 8, 2004 in response to the BPAI decision mailed on November 10, 2004. Timeliness and receipt of this response by the U.S. PTO were evidenced by the Applicants' receipt of the postcard which was date-stamped January 8, 2004 by the U.S. PTO. The reply and terminal disclaimer addressed the rejections that were affirmed in the BPAI decision, which were the rejection of claim 33 under 35 U.S.C.

§112, second paragraph, and the provisional obviousness double patenting rejection of claims 21-30 and 33 based on copending Application No. 09/547,802. The Examiner indicated that there was no record of a reply/terminal disclaimer in the electronic application file and that she would discuss this issue with her supervisor.

On May 3, 2004, Applicants contacted the Examiner and pursuant to her request faxed a copy of the reply/terminal disclaimer/returned postcard. The Examiner confirmed receipt of the faxed papers, but indicated that she was trying to locate the paper application file to match up the faxed papers with the paper file. The Examiner further indicated that since the reply/terminal disclaimer were timely received by the U.S. PTO on January 8, 2004 and subsequently lost by the U.S. PTO, that this was an error that should be corrected by the U.S. PTO. To this end, the Examiner made clear that she would handle this matter and that Applicants did not have to file any petition or RCE in response to the Notice of Abandonment. Applicants relied on the Examiner's statement that this matter would be handled by her and that no other papers were required to be filed by Applicants to address the Notice of Abandonment.

On June 17, 2004, Applicants contacted the Examiner to follow-up on the status of the application. The Examiner indicated that the paper application file was still missing and was not returned to her. To expedite return of the paper application file to her, the Examiner advised Applicants to call the Head of Administration, Margaret Stevens, or the Examiner's supervisor. On June 17, 2004, Applicants left a voice mail message with the Head of Administration, but the Head of Administration did not return the call.

On June 23, 2004, Applicants left a voice mail message with the Examiner's supervisor requesting help in retrieving the paper application file. On June 24, 2004, the Examiner's supervisor contacted Applicants and indicated that in response to the Notice of Abandonment Applicants must file a petition to revive the application with proof that the reply/terminal disclaimer was timely received.

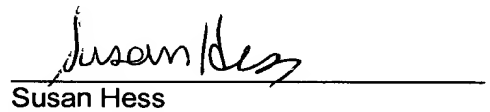
In summary, the reply/terminal disclaimer were timely received by the PTO within two months of the mail date of the BPAI decision as evidenced by the date-stamped postcard sent by the PTO. Copies of the BPAI decision mailed on November 10, 2003 and the reply/terminal disclaimer mailed on January 8, 2004 in response to the decision are enclosed herewith. In addition, Applicants exercised due diligence in monitoring the status of the application within the two month period in which a petition to withdraw the holding of abandonment was due and following that period. This was evidenced by repeatedly contacting the Examiner and other PTO employees and resubmitting to the Examiner on May 3, 2004 copies of the reply/terminal disclaimer/returned postcard. Copies of the faxed reply/terminal disclaimer/returned postcard are enclosed herewith. Further, while Applicants appreciated the Examiner's efforts to facilitate prosecution and rectify this matter, Applicants detrimentally relied on the Examiner's statement that the matter would be handled by her and that no further action was necessary by Applicants.

Such reliance was a major factor which led to the loss of valuable time and to the failure to submit a petition to withdraw the holding of abandonment within two months from the mail date of the Notice of Abandonment.

In view of the above, it is respectfully requested that the holding of abandonment of the application be withdrawn. It is further requested that since a timely reply in response to the BPAI decision was received and then lost by the U.S. PTO, and Applicants were diligent in monitoring the status of the application and relied on the Examiner's statement that no further action was necessary by Applicants, the requirement of providing a terminal disclaimer with the petition be waived. In the event that a terminal disclaimer is deemed to be required, the terminal disclaimer will be provided upon notification by the U.S. PTO.

No fee is believed to be due; however, in the event a fee is deemed to be required, please charge the required fee to Deposit Account No. 19-0134 in the name of Novartis.

Respectfully submitted,



Susan Hess
Attorney for Applicants
Reg. No. 37,350

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7859

Date: July 15, 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,212	12/15/2000	Klaus Neuer	4-118-8353B/C1	9685

7590 03/15/2004

EXAMINER
WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/15/2004

Thomas Hoxie
Novartis Corporation
Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027

TRS

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Abandonment

Application No.	Applicant(s)	
09/738,212	NEUER ET AL.	
Examiner	**Art Unit**	
Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☐ Applicant's failure to timely file a proper reply to the Office letter mailed on _____.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☐ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☒ The decision by the Board of Patent Appeals and Interference rendered on *10 November 2003* and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

[redacted] -CO[redacted]JOURNAL- ********** DATE MAY-03-[redacted] ***** TIME 13:54 *********

MODE = MEMORY TRANSMISSION START=MAY-03 13:52 END=MAY-03 13:54

FILE NO.=413

STN NO.	COMM.	ONE-TOUCH/ ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
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-NOVARTIS INTELLECT PROP -

********** - - ***** - 973 781 8064- **********

Susan Hess Ph.D.
Senior Patent Attorney

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Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover NJ 07936-1080

Tel (862) 778-7859
Fax (973) 781-8064
Internet: susan.hess
@group.novartis.com

NOVARTIS

Fax

Attention: Examiner Lauren Wells
U.S. Patent and Trademark Office
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Fax no.: 571-273-0634
Number of pages: including cover page-7 pages

Date: May 3, 2004

Concerning: **Re: Application Ser. No. 09/738,212 (Case 4-118-8353B)-Resubmission of Reply and Terminal Disclaimer**

Pursuant to your request, attached is the reply and terminal disclaimer that was previously filed on January 8, 2004.

Respectfully submitted,

Susan Hess

Susan Hess

SH:

NOVARTIS

Susan Hess Ph.D.
Senior Patent Attorney

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover NJ 07936-1080

Tel (862) 778-7859
Fax (973) 781-8064
Internet: susan.hess
@group.novartis.com

Fax

Attention: Examiner Lauren Wells
U.S. Patent and Trademark Office
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Fax no. 571-273-0634

Number of pages: including cover page-7 pages

Date: May 3, 2004

Concerning: **Re: Application Ser. No. 09/738,212 (Case 4-118-8353B)-Resubmission of Reply and Terminal Disclaimer**

Pursuant to your request, attached is the reply and terminal disclaimer that was previously filed on January 8, 2004.

Respectfully submitted,

Susan Hess

Susan Hess

SH:

CASE 4-118-8353B

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Susan Hess	Susan Hess	May 3, 2004
Type or print name	Signature	Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
NEUER ET AL.
APPLICATION NO: 09/738,212
FILED: DECEMBER 15, 2000
FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID

Art Unit: 1617
Examiner: A. Berman

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

COMMUNICATION

Sir:

As requested by the Examiner and in response to the Notice of Abandonment mailed March 15, 2004, Applicants resubmit the reply and terminal disclaimer that was filed on January 8, 2004 in response to the BPAI decision dated November 10, 2003. A copy of the date-stamped postcard indicating that the reply was timely received by the U.S. PTO is also attached.

Respectfully submitted,

Susan Hess

Susan Hess
Attorney for Applicants
Reg. No. 37,350

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7859

Date: May 3, 2004

CASE 4-118-8353B

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV336721095US
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Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
NEUER ET AL.
APPLICATION NO: 09/738,212
FILED: DECEMBER 15, 2000
FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID

Art Unit: 1617
Examiner: Lauren Wells

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

REPLY

Sir:

This is in response to the BPAI decision dated November 10, 2003.

Cancel claims 31-33 without prejudice to applicants' rights thereto.

The remaining claims are 21-30, which stand rejected solely for double patenting over application 09/547,802. Attached is a Terminal Disclaimer over said application, which moots the rejection.

Respectfully submitted,

Gabriel Lopez
Attorney for Applicants
Reg. No. 28,440
(862) 778-7882

Novartis
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One Health Plaza, Building 430
East Hanover, NJ 07936-1080

encl: Term Disc. + fee letter

Date: 1/8/04

CASE 4-118-8353B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
NEUER ET AL.
APPLICATION NO: 09/738,212
FILED: DECEMBER 15, 2000
FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID

Art Unit: 1617
Examiner: Lauren Wells

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

FEE LETTER

Sir:

Enclosed is a Terminal Disclaimer in the above-identified application.

The Commissioner is hereby authorized to charge the $110 fee under 37 CFR §1.20(d) and any additional fees that may be required to Deposit Account No. 19-0134 in the name of Novartis. An additional copy of this paper is enclosed.

Respectfully submitted,

Gabriel Lopez
Attorney for Applicants
Reg. No. 28,440
(862) 778-7882

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080

Date: 1/8/04

CASE 4-118-8353B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
NEUER ET AL.
APPLICATION NO: 09/738,212
FILED: DECEMBER 15, 2000
FOR: PHARMACEUTICAL COMPOSITIONS OF MACROLIDES OR CYCLOSPORINE WITH A POLYETHOXYLATED SATURATED HYDROXY-FATTY ACID

Art Unit: 1617
Examiner: Lauren Wells

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

TERMINAL DISCLAIMER

Sir:

Novartis AG, a company organized under the laws of the Swiss Confederation, having a place of business at Lichtstrasse 35, Basel, Switzerland 4056, represents that it is the assignee and owner of the entire interest in the above-identified application by virtue of an assignment which is being transmitted for recordation in the United States Patent and Trademark Office concurrently herewith. A copy is attached hereto.

Novartis AG hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified application which would extend beyond the expiration date of the full statutory term defined in 35 USC §154-156 and §173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending **Application No. 09/547,802** filed April 11, 2000. Said Application No. 09/547,802 is also assigned to Novartis AG (formerly Sandoz Ltd.) by virtue of an assignment which was recorded in the United States Patent and Trademark Office on June 27, 1994 at Reel/Frame 7041/0439.

Novartis AG hereby agrees that any patent granted on the above-identified application shall be enforceable only for and during such period that it and any patent granted on Application No. 09/547,802 are commonly owned. This agreement runs with any patent granted on the above-identified application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, Novartis AG does not disclaim the terminal part of any patent granted on the above-identified application that would extend to the expiration date of the full statutory term as defined in 35 USC §154-156 and §173 of any patent granted on Application

No. 09/547,802, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR §1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

A terminal disclaimer fee under 37 CFR §1.20(d) is included.

Signed this 8th day of January, 2004 by the undersigned attorney of record.

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080

Melvyn M. Kassenoff

Melvyn M. Kassenoff
Attorney for Applicants
Reg. No. 26,389
(862) 778-7862

Encl: Assignment

Case No. 4-118-8353A

Application No. 09/738,212

Mailing Date: 1/8/2004

Due Date: 1/10/2004

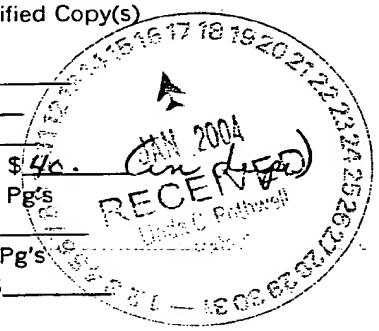
Express Mail No.: EV 336721095US

The Patent & Trademark Office acknowledges, and has stamped hereon the date of receipt of the items checked below:

- ☑ Amendment/Response/Letter - Fee $_____
- ☐ Appln. Filing Papers - Fee $_____
  - ☐ PCT National Stage
  - ☐ Provisional Application
  - ☐ RCE ☐ DIV ☐ CONT ☐ CIP
  - ☐ Specification _____ Pg's
- ☐ Executed/Unexecuted Decl. - Fee $_____
  - ☐ Missing Parts/Missing Req.
- ☐ Preliminary Amendment _____ Pg's
- ☐ Claim of Priority ☐ Certified Copy(s)
- ☐ Amendment After Final
- ☐ Notice of Appeal - Fee $_____
- ☐ Appeal Brief - Fee $_____
- ☐ Issue Fee Payment $_____
- ☑ Assignment Rec. Req. - Fee $40.
- ☐ Formal Drawings _____ Pg's
- ☐ IDS_____ Pg's - Fee $_____
- ☐ PTO-1449 Form _____ Pg's
- ☐ Pet. for Ext. of Time - Fee $_____
- ☐ Application Data Sheet
- ☐ Seq. Listings _____ Pg's/Seq. Disk
- ☑ Terminal Disclaimer; Reply;
- ☐ See Letter in Dup.

GL
Initials

82972/99A Rev.1



The opinion in support of the decision being entered today was ***not*** written for publication and is ***not*** binding precedent of the Board.

4-118-8353B

Paper No. 18

SL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KLAUS NEUER, MONIKA PETSZULAT and HATTO WALCH

Appeal No. 2003-1422
Application 09/738,212

ON BRIEF

Before WILLIAM SMITH, GRIMES, and POTEATE, ***Administrative Patent Judges.***

POTEATE, ***Administrative Patent Judge.***

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 21-30 and 33. Claims 31 and 32 are also pending, but have been withdrawn from consideration as directed to a non-elected invention. Claims 21 and 33 are representative of the subject matter on appeal and are reproduced below:

21. A hard gelatin capsule comprising
(a) a cyclosporin as active ingredient,
(b) a polyethoxylated saturated hydroxy-fatty acid, and
(c) a C_2-C_3 alcohol having one or two hydroxy groups.

33. A hard gelatin capsule of claim 21 further comprising
(d) mono-, di- and/or triesters of fatty acids, and optionally
(e) ricinoleic acid glyceride(s) together with smaller proportions of multiply unsaturated fatty acid glycerides or caster oil
as a unit dosage form.

The references relied upon by the examiner are:

Orbán et al. (Orbán)	5,047,396	Sept. 10, 1991
Hauer et al. (Hauer)	5,342,625	Aug. 30, 1994

GROUNDS OF REJECTION

1. Claim 33 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

We affirm.

2. Claims 21-30 and 33 stand rejected under 35 U.S.C. § 103 as unpatentable over Orbán in view of Hauer.

We reverse.

3. Claims 21-30 and 33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/690,400.

We reverse.

4. Claims 21-30 and 33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 09/605,512.

We vacate.

5. Claims 21-30 and 33 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 15, 17, 19, 24, 26 and 28 of copending Application No. 09/547,802.

We affirm.

BACKGROUND

The invention relates to a hard gelatin capsule comprising cyclosporin as the active ingredient, a poly-ethoxylated saturated hydroxy-fatty acid and a C_2-C_3 alcohol. Claim 21. Cyclosporins possess anti-inflammatory and anti-parasitic activity and are used for a variety of applications which include the treatment of inflammatory disorders and various auto-immune diseases. Specification, page 1.

Cyclosporins have a strongly hydrophobic character and are difficult to process with the usual pharmaceutical excipients

to form preparations having sufficient bioavailability. *Id.*, page 2. It is known to administer cyclosporin intravenously. *Id.*, page 3. However, a disadvantage of intravenous preparations is that they must be administered in clinics by trained personnel. *Id.* Oral preparations, though more easily administered, suffer from the drawback of low and variable bioavailability. *Id.*, page 4. See Hauer, column 3, lines 57-61. According to appellants, the claimed oral cyclosporin preparation provides comparable bioavailability to intravenously administrable preparations. Specification, page 7.

DISCUSSION

1. Rejection of claim 33 under 35 U.S.C. § 112, second paragraph, as indefinite

According to the examiner, claim 33 is vague and indefinite because it is unclear what appellants are claiming for component (e). Examiner's Answer, Paper No. 14, mailed January 15, 2003, page 3. In particular, the examiner maintains that it is unclear as to whether appellants are claiming a combination of ricinoleic acid glycerides and multiply unsaturated fatty acid glycerides, or castor oil, or whether appellants are claiming a mixture of ricinoleic acid glycerides

with multiply unsaturated fatty acid glycerides, or a mixture of ricinoleic acid glycerides with castor oil. While appellants attempt to explain what is intended by this language (see Appeal Brief, Paper No. 13, received October 16, 2002, page 2), we are in agreement with the examiner that the claim language is indefinite. In fact, even upon reading appellants' explanation as to what is intended by this language, we are still unclear as to what is being claimed. We are further in agreement with the examiner that the language "smaller proportions of multiply unsaturated fatty acid glycerides" is indefinite as it is unclear what the basis for comparison is. See Examiner's Answer, page 3.

2. Rejection of claims 21-30 and 33 under 35 U.S.C. § 103 as unpatentable over Orbán in view of Hauer

It is the examiner's position that Orbán discloses the cyclosporin composition of claim 21, but fails to teach that the composition may be provided in a hard gelatin capsule. See Examiner's Answer, page 8. The examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of the invention to have prepared Orbán's composition in a hard gelatin capsule in view of the teachings of Hauer. *Id.*, page 5. In particular, the examiner notes that Hauer is directed to pharmaceutical compositions comprising cyclosporins which include

an alcohol and may contain a single surfactant, such as polyoxyethylene stearic acid ester. ***Id.***, page 4. Hauer's composition may be provided in hard or soft gelatin capsules. ***Id.***

Appellants argue that Orbán's disclosure is limited to a cyclosporin containing composition for intravenous administration. Appeal Brief, page 3.[1] According to appellants, "[t]here is no teaching or suggestion that this composition may also be advantageous with respect to stability and bioavailability in medicaments for oral administration." ***Id.*** While appellants do not dispute the examiner's finding that Hauer discloses a cyclosporin-containing composition in a hard gelatin capsule, they maintain that there would have been no motivation to have combined the teachings of Orbán and Hauer since Orbán fails to disclose or suggest that his composition may also be used for oral administration. Appeal Brief, page 3.

"[T]he question under 35 U.S.C. § 103 is not merely what the references expressly teach, but what they would have

[1]Appellants also note that one of the differences between Hauer's composition and that of the claimed invention is that the present invention requires a polyethoxylated saturated hydroxy-fatty acid component which is not taught by Hauer. ***Id.***

suggested to one of ordinary skill in the art at the time the invention was made." ***In re Lamberti***, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976). In order to establish a ***prima facie*** case of obviousness, the examiner must identify a suggestion or motivation to modify the teachings of the cited references to achieve the claimed invention. ***In re Kotzab***, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). The suggestion or motivation to modify a reference may be implicit from the prior art as a whole rather than expressly stated. ***Id.*** However, regardless of whether the examiner relies on an express or implicit showing, he must provide reasons for finding a limitation to be taught or suggested in the reference. ***Id.***

We are in agreement with appellants, that the examiner has failed to satisfy his burden of identifying a suggestion or motivation to modify the teaching of Orbán in view of Hauer to achieve the claimed invention. In support of his proposed combination, the examiner states that

> [i]t would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '396 in a hard gelatin capsule as taught by US '625 with the reasonable expectation of obtaining a cyclosporin composition that provides convenient oral administration and

> improved bioavailability. [Examiner's Answer, page 5.]

However, the examiner has failed to identify any support in the references for this conclusion. In reviewing Orbán, we are in agreement with appellants that the reference is clearly limited to an intravenous pharmaceutical composition. See, e.g., Orbán, column 2, lines 9-14 ("Therefore our aim was to work out an intravenous pharmaceutical composition comprising cyclosporin as active ingredient which is more tolerable than the known intravenous formations, i.e., its anaphylactic-hypersenzibilizing effect is smaller than that of the known formulation."). By contrast, Hauer is strictly limited to a cyclosporin containing composition which is suitable for use in topical formulations and, in particular, oral dosage forms. See Abstract.

Having found that the examiner has failed to establish a ***prima facie*** case of obviousness, the rejection is reversed.

3. ***Provisional rejection of claims 21-30 and 33 under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/690,400***

Application No. 09/690,400 issued as U.S. Patent No. 6,258,808 on July 10, 2001. We have reviewed the claims of the issued patent and have concluded that they are not directed to the same invention claimed in present claims 21-30 and 33, and do not render obvious claims 21-30 and 33.

The rejection is reversed.

4. ***Provisional rejection of claims 21-30 and 33 under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 09/605,512***

Application No. 09/605,512 was abandoned on March 26, 2002. Accordingly, we vacate this ground of rejection.

5. ***Provisional rejection of claims 21-30 and 33 under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-3, 5-8, 15, 17, 19, 24, 26 and 28 of copending Application No. 09/547,802***

Appellants fail to present arguments traversing this ground of rejection. See Appeal Brief, page 4. Accordingly, the rejection is affirmed.

In sum, we affirm the rejection of claim 33 under 35 U.S.C. § 112, second paragraph, and affirm the provisional obviousness-type double patenting rejection of claims 21-30 and 33 based on copending Application No. 09/547,802. We reverse the provisional obviousness-type double patenting rejection based on Application No. 09/690,400, now patented. We vacate the provisional rejection of claims 21-30 and 33 under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1 and 2 of Application No. 09/650,512, now abandoned. We reverse the rejection of claims 21-30 and 33 under 35 U.S.C. § 103 as unpatentable over Orbán in view of Hauer.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

WILLIAM F. SMITH
Administrative Patent Judge

ERIC GRIMES
Administrative Patent Judge

LINDA R. POTEATE
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

LRP:psb

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 14
mailed on
date. 1-15-03

Application Number: 09/738,212
Filing Date: December 15, 2000
Appellant(s): NEUER ET AL.

Gabriel Lopez
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 16, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 21-30 and 33 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,047,396 A	ORBAN et al.	9-1991
5,342,625 A	HAUER et al.	8-1994

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the appellant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention.

Claim 33 is vague and indefinite because it is unclear what appellant intends to claim for component (e). Is component (e) either a combination of ricinoleic acid glyceride(s) and multiply unsaturated fatty acid glycerides or castor oil or is it a mixture of ricinoleic acid glyceride(s) with multiply unsaturated fatty acid glycerides or a mixture of ricinoleic acid glyceride(s) with castor oil? Additionally, in relation to what are the proportions of multiply unsaturated fatty acid glycerides smaller?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,047,396 (396) in combination with US 5,342,625 (625).

US '396 discloses a pharmaceutical composition comprising 1 part cyclosporin, 8 to 13 parts of a polyethylene glycol saturated hydroxy fatty acid, and 4 to 10 parts of a mono- or polyvalent alcohol (abstract). Cyclosporin A is disclosed at column 2, lines 44-47. Alcohols that may be present as co-solvents in the composition are ethanol and propylene glycol (col. 3, lines 1-5). Various excipients can be used in the formulation (col. 3, lines 15-16). Example 1 teaches 65 g of Solutol® HS 15 (polyethylene glycol-

660-12-hydroxystearate), 30 ml of ethanol and 5 g of cyclosporin A. Ethanol is added to 100 ml. The composition of example 1 comprises 65% polyethylene glycol-660-12-hydroxystearate, 5% cyclosporin A and 30% ethanol. See also claim 6 for polyethylene glycol-660-12-hydroxy stearate and claim 7 for ethanol and propylene glycol. US '396 does not teach the composition in a capsule.

US '625 is directed to pharmaceutical compositions comprising cyclosporins (title). For Cyclosporin A and additional cyclosporins, see column 2, line 61 to column 3, line15. The composition comprises a hydrophilic phase, a lipophilic phase and a surfactant (col. 6, lines 45-50). For propylene glycol as the hydrophilic phase, see column 7, lines 21-25. For additional alcohols in the hydrophilic phase such as ethanol, see column 8, lines 25-35. For polyoxyethylene stearic acid esters as surfactants, see column 9, lines 40-44 and column 10, lines 31-32. US '625 teaches at column 12, lines 16-17 that the composition may contain a single surfactant, i.e. a polyoxyethylene stearic acid ester. For hard and soft gelatin capsules, see column 16, lines 25-28. For ratios of components, see column 17, line 50 to column 18, line 20. The ratio of cyclosporin (a) to hydrophilic phase (c) is 1:0.2-10 p.p.w. (col. 17, lines 50-54). The ratio of cyclosporin to surfactant (b) is 1:0.5-20 (col. 18, lines 13-20). Therefore, the ratio of (a):(b):(c) is 1: 0.5-20: 0.2-10, which overlaps the instantly claimed ratios. US '625 teaches fatty acid triglycerides (triesters of fatty acids) as the lipophilic phase at column teaches fatty acid triglycerides (triesters of fatty acids) as the lipophilic phase at column 8, lines 56-65 and mono-, di- and mono/diglycerides as surfactants at column 11, lines 36-52.

US '396 teaches a composition containing cyclosporin A, polyethylene glycol-660-12-hydroxystearate, ethanol and propylene glycol. US '625 teaches that compositions containing a cyclosporin, a polyethoxylated hydroxy fatty acid ester surfactant, ethanol and propylene glycol can be provided in a hard gelatin capsule.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '396 in a hard gelatin capsule as taught by US '625 with the reasonable expectation of obtaining a cyclosporin composition that provides convenient oral administration and improved bioavailability.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/690400. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to compositions comprising cyclosporin, a C_2-C_3 alcohol and a surfactant. The

applications differ in that 09/690400 is claiming also a mixed mono-, di-, triglyceride. The instant application discloses mono-, di-, and triesters of fatty acids for use in the compositions. See claim 3. Glycerides are esters. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the composition of the instant application and add mixed mono-, di-, triglyceride as disclosed in 09/690,400 expecting to obtain a oral dosage form containing cyclosporin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 09/605512. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a composition comprising cyclosporin a polyethoxylated hydroxy fatty acid ester surfactant and an alcohol.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 15, 17, 19, 24, 26 and 28 of copending Application No. 09/547802. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a composition comprising cyclosporin, an alcohol and a surfactant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(11) Response to Argument

Appellant argues that it is clear from instant claim 33 that optional component (e) is either ricinoleic acid glycerides(s) with multiply unsaturated fatty acid glycerides or ricinoleic acid glycerides(s) with castor oil. It is the Examiner's position that a fair reading of this claim does not provide a clear and concise depiction of Appellant's intention. It is not clear if component (e) can be ricinoleic acid glycerides(s) with castor oil or castor oil alone. Appellant's intent is unclear. It appears that this may be a situation where a broad limitation is claimed together with a narrow limitation. See *ex Parte Wu*, 10 USPQ2d 2300 (BdApls 1989) at 2303. The Board stated that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required or (b) a required feature of the claim. In this instance, claim 33 recites the broad limitation castor oil and also recites the narrower limitation ricinoleic acid glycerides. The chief constituent of castor oil is ricinolein (glyceride of ricinoleic acid). Therefore, the incorporation of castor oil into the composition would include the incorporation of ricinoleic acid glycerides.

Appellant argues that it is clear from instant claim 33 that the unsaturated fatty acid glycerides are present in an amount lesser than ricinoleic acid glyceride(s). It is the Examiner's position that this is not clear from a fair reading of the instant claim. The

amount of unsaturated fatty acid glycerides could be in relation to any other component in the composition. The claim is indefinite.

In response to appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, US '396 teaches the composition instantly claimed, albeit for injection, and US '625 teaches that compositions like those disclosed in US '396 are useful for oral administration and can be provided in hard gelatin capsules. US '396 also teaches at column 1 that it is known in the art to orally administer cyclosporin. The motivation to combine the references is to provide convenient oral administration of a cyclosporin composition.

Appellant argues that there is no motivation to use the compositions of US '396 for oral administration. The instant invention is drawn to a product. The future intended use of that product does not provide patentability to the claims. Terms merely setting forth an intended use for, or a property inherent in, an otherwise old composition do not differentiate the claimed composition from those of the prior art. *In re Pearson*, 181 USPQ 641. Difference in use cannot render claimed composition novel. *In re Tuominen*, 213 USPQ 89. As stated above, US '396 teaches the composition instantly claimed. US '625 teaches that compositions like those disclosed in US '396 can be provided in hard

gelatin capsules. The prior art teaches that compositions containing the same components as instantly claimed can be provided in hard gelatin capsules.

Appellant argues that US '396 does not teach the additional component of instant claim 33, mono-, di- and/or triesters of fatty acids. This argument is not convincing because US '625 teaches that monoglycerides, diglycerides and triglycerides of fatty acids, which are esters of fatty acids and glycerol, can be used alone or in combination in cyclosporin pharmaceutical compositions. Thus, US '625 makes up this deficiency in US '396.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the prior art teaches all of the limitations instantly claimed.

Appellant argues that the double patenting rejections are provisional and cannot be resolved until allowability is indicated. Because Appellant has not provided any substantive arguments why the double patenting rejections are improper, they are maintained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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January 10, 2003

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